General Indications for Implantable Cardioverter Defibrillators

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Current FDA Label Indications

- The implantable cardiac defibrillator (ICD) is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations:
  - Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia; or
  - Recurrent, poorly tolerated, sustained ventricular tachycardia.

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Current FDA Label Indications

- One company, Guidant, has indications for an additional patient population:
  - Prior MI, LVEF≤35%, documented episode of NSVT with an inducible tachyarrhythmia
    - Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied

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Proposed Label Indications From FDA Panel Pack

- Functional indication
  - "The ICD is intended to provide (ventricular antitachycardia pacing and) ventricular defibrillation, for automated treatment of life-threatening ventricular arrhythmias."
- No statement of which patients are at risk for life-threatening ventricular arrhythmias

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FDA Rationale For Proposed Change In Label Indications

- Current indications for use are not consistent with current practice
  - "The current label indications do not incorporate some of the clinical information which is widely available and which forms the basis for current practice."
- More accurate label
  - "...the label will be more accurate if the stated indication is for the device's known functionality, and does not attempt to define the population at risk."
- Precedent for use of general functional indications exists
  - Coronary balloon angioplasty catheters and heart valves

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Potential Advantages
Clinician Perspective

- The decision to implant an ICD is a medical decision made by patients and their physicians based on the most current clinical evidence and what is most appropriate for the individual patient.
- FDA role is focused on establishing the safety and effectiveness of ICDs.
- Current public and private payer coverage is broader than current label indications.

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Potential Advantages
Clinician Perspective

- Manufacturers able to assist in the timely dissemination of clinical evidence relating to the use of ICD therapy
  - For patient populations identified in Section IV of the panel pack (e.g. HCM, LQTS, MUSTT)
  - For future at-risk patient populations as new clinical trials are completed

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Potential Disadvantages
Clinician Perspective

- Potential for "over-use" of ICDs
  - Medical community has safeguards against "over-use"
    - Physicians actively seek out the latest clinical evidence
    - ACC/AHA, NASPE guidelines
    - Proposed label change does not affect coverage & reimbursement policies of payers who rely on clinical evidence

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Medtronic Position

- Medtronic agrees that the proposed functional ICD labeling, as described in the panel pack, should be adopted.

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Potential Advantages
Industry Perspective

- Consistent indications for use across manufacturers' PMA-approved ICDs
- Promote industry cooperation in supporting clinical trials
- Allows rapid dissemination of clinical trial results without the need for FDA approval (e.g. no PMA-S)

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Potential Advantages
Industry Perspective

- Reduces regulatory burden
- Consistent with "least burdensome" provisions of FDAMA
  - New studies of at-risk patient populations would not require an IDE application
  - No need for PMA supplements prior to dissemination of clinical trial results for every specific at-risk patient population studied
- Allows FDA to focus on new product approvals

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Potential Disadvantages
Industry Perspective

- Could discourage clinical research on specific high-risk patient populations. But...
  - Manufacturers are committed to supporting clinical research
    - Physicians' clinical decision making relies on clinical evidence
    - Payers' technology assessment requirements
    - Ongoing studies (SCD-HeFT, IRIS, HCM, LQTS)
  - Physicians are highly committed to continued research to identify appropriate patients most likely to benefit from ICD therapy

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Summary

- Medtronic strongly supports the proposed change to a functional indication for ICDs
  - Consistent with current clinical practice and knowledge base
  - Enhances timely dissemination of clinical trial data
  - Decreases regulatory burden

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HCFA ICD Coverage Effective 7/1/1999

Patients with the following conditions:

1. A documented episode of cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause;
2. Ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or
3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias such as long QT syndrome or hypertrophic cardiomyopathy.

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